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510(k) Summary – Oracle Spacer

510(k) Summary – Oracle Spacer	
Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Stacey Bonnell Associate Regulatory Affairs Specialist Telephone: 610-719-5895 Facsimile: 610-719-5102 Email: bonnell.stacey@synthes.com
Date Prepared:	December 21, 2007
Trade Name(s):	Synthes Oracle Spacer
Classification:	21 CFR 888.3080 – Spinal Intervertebral Body Fusion Orthopaedic and Rehabilitation Devices Panel Product Code MAX Class II 21 CFR 888.3060 – Spinal Vertebral Body Replacement Device Orthopaedic and Rehabilitation Devices Panel Product Code MQP Class II
Predicates:	Depuy Acromed, Inc., Lumbar I/F Cage (P960025)
Device Description(s):	The **Synthes Oracle Spacer** is a radiolucent, oval-shaped interbody fusion device used in conjunction with supplemental fixation to provide structural stability in skeletally mature individuals following total or partial discectomy. The Oracle Spacer implant may be used to accommodate the anatomical requirements of the intervertebral disc space. Pyramidal teeth that assist in further stabilization of the construct are located on the inferior and superior surfaces of the spacer. The open architecture of the device is intended to be packed with autogenous bone graft (i.e. autograft).

510(k) Summary – Oracle Spacer	
Intended Use/ Indications for Use:	**Synthes Oracle Spacer** is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1 whose condition requires the use of interbody fusion combined with supplemental fixation. The interior of the Oracle Spacer should be packed with autogenous bone graft (i.e. autograft). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. *The Oracle Spacer is intended to be used with Synthes supplemental fixation, e.g. TSLP, ATB, Antegra, Pangea, USS (including Click'X) and small stature USS. **Synthes Oracle Spacer** is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a diseased vertebral body resected or excised during partial and total vertebrectomy procedures or the treatment of tumor or trauma (i.e. fracture), to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of the collapsed vertebral body. The Oracle Spacer is intended to be used with Synthes internal fixation systems, e.g., Pangea, USS 9including Click'X), Small Stature USS, ATLP, TSLP, and VentroFix. The interior of the spacer can be packed with bone (autograft or allograft). The Oracle Spacer is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.
Comparison of the device to predicate device(s):	Synthes Oracle Spacer is substantially equivalent to the predicate(s) in design, function, performance, and material. Synthes Oracle Spacer is similar to Depuy AcroMed's Lumbar I/F Cage (P960025) with regards to Indications for Use.
Performance Date (Non-Clinical and/or Clinical):	*Non-Clinical Performance and Conclusions:* Based on information contained herein, Synthes has determined that the Synthes Oracle Spacer is substantially equivalent to the predicate device(s). *Clinical Performance and Conclusions:* Clinical data and conclusions were not needed for this device.

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510(k) Summary – OPAL Spacer

510(k) Summary – OPAL Spacer	
Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Stacey Bonnell Associate Regulatory Affairs Specialist Telephone: 610-719-5895 Facsimile: 610-719-5102 Email: bonnell.stacey@synthes.com
Date Prepared:	December 21, 2007
Trade Name(s):	Synthes OPAL Spacer
Classification:	21 CFR 888.3080 – Spinal Intervertebral Body Fusion Orthopaedic and Rehabilitation Devices Panel Product Code MAX Class II 21 CFR 888.3060 – Spinal Vertebral Body Replacement Device Orthopaedic and Rehabilitation Devices Panel Product Code MQP Class II
Predicates:	Depuy Acromed, Inc., Lumbar I/F Cage (P960025)
Device Description(s):	**Synthes OPAL Spacer** is a radiolucent, rectangular shaped interbody fusion device used in conjunction with supplemental fixation to provide structural stability in skeletally mature individuals following total or partial discectomy. The OPAL Spacer construct is convex in shape to closely resemble patient anatomy and ensure accurate sizing. The implants have bulleted noses, and trial spacers facilitate self-distraction and insertion. The open architecture of the device is intended to be packed with autogenous bone graft (i.e. autograft).

510(k) Summary – OPAL Spacer	
Intended Use/ Indications for Use:	**Synthes OPAL Spacer** is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1 whose condition requires the use of interbody fusion combined with supplemental fixation. The interior of the OPAL Spacer should be packed with autogenous bone graft (i.e. autograft). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. *The OPAL Spacer is intended to be used with Synthes supplemental fixation, e.g. TSLP, ATB, Antegra, Pangea, USS (including Click'X) and small stature USS. **Synthes OPAL Spacer** is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). The OPAL Spacer is intended to be used with Synthes supplemental internal fixation systems, e.g., ATLP, VentroFix and USS. The interior of the spacer component of the OPAL Spacer system can be packed with bone.
Comparison of the device to predicate device(s):	Synthes OPAL Spacer is substantially equivalent to the predicate(s) in design, function, performance, and material. Synthes OPAL Spacer is similar to Depuy AcroMed's Lumbar I/F Cage (P960025) with regards to Indications for Use.
Performance Date (Non-Clinical and/or Clinical):	*Non-Clinical Performance and Conclusions:* Based on information contained herein, Synthes has determined that the Synthes OPAL Spacer is substantially equivalent to the predicate device(s). *Clinical Performance and Conclusions:* Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Synthes Spine
% Ms. Stacey Bonnell
Associate Regulatory Affairs Specialist
1302 Wrights Lane East
West Chester, Pennsylvania 19380

MAY 17 2012

Re: K072791
Trade/Device Name: Synthes Oracle and OPAL Spacers
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: September 28, 2007
Received: October 1, 2007

Dear Ms. Bonnell:

This letter corrects our substantially equivalent letter of December 26, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not

limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®
Spine

Indications for Use Statement – Synthes Oracle Spacer

510(k) Number: K072791

Device Name: Synthes Oracle Spacer

Indications for Use:

Synthes Oracle Spacer is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1 whose condition requires the use of interbody fusion combined with supplemental fixation. The interior of the Oracle Spacer should be packed with autogenous bone graft (i.e. autograft).
DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

*The Oracle Spacer is intended to be used with Synthes supplemental fixation, e.g. TSLP, ATB, Antegra, Pangea, USS (including Click'X) and small stature USS.

Synthes Oracle Spacer is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a diseased vertebral body resected or excised during partial and total vertebrectomy procedures for the treatment of tumor or trauma (i.e. fracture), to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of the collapsed vertebral body. The Oracle Spacer is intended to be used with Synthes internal fixation systems, e.g., Pangea, USS (including Click'X), Small Stature USS, ATLP, TSLP, and VentroFix. The interior of the spacer can be packed with bone (autograft or allograft).

The Oracle Spacer is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

Prescription Use X (21 CFR 801 Subpart D)	AND / OR	Over-the-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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510(k) Number K072791

Indications for Use Statement – OPAL Spacer

SYNTHES® Spine

510(k) Number(s): K072791
(if known)

Device Name: **Synthes OPAL Spacer**

The OPAL Spacer is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1 whose condition requires the use of interbody fusion combined with supplemental fixation. The interior of the OPAL Spacer should be packed with autogenous bone graft (i.e. autograft). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

*The OPAL Spacer is intended to be used with Synthes supplemental fixation, e.g. TSLP, ATB, Antegra, Pangea, USS (including Click'X) and small stature USS.

The OPAL Spacer is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). The OPAL Spacer is intended to be used with Synthes supplemental internal fixation systems, e.g., ATLP, VentroFix and USS. The interior of the spacer component of the OPAL Spacer system can be packed with bone.

Prescription Use X (21 CFR 801 Subpart D) AND / OR Over-the-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Catherine Brosenitsch for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072791

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